

Paravertebral nerve blocks for analgesia after cardiac surgery

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| Submission date 10/07/2015 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/07/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/06/2017 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The aim of this study is to find out whether injecting a local anaesthetic into the back to block the nerves to the chest (a paravertebral injection) reduces pain after cardiac surgery. This is a technique of pain control the trialists have been using recently and it sounds sensible, but it's hard to be sure that it really works because there are such big differences in the amount of pain people experience after cardiac surgery. What's more, just getting local anaesthetics into the blood stream reduces pain after other surgical operations, so it may be that paravertebral injections are working simply because the drug is being absorbed into the blood. This study is designed to clarify the situation.

Who can participate?

Patients undergoing coronary artery bypass grafting.

What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 are given bilateral paravertebral blocks during surgery. Those in group 2 are given a dummy, or 'sham', injection under the skin. After surgery, patients are able to self-administer pain relief (morphine) as they need it, to see whether the patients with true paravertebral injections want less morphine than those with the sham injections.

What are the possible benefits and risks of participating?

It is hoped that all patients taking part get additional benefit from the local anaesthetic infusion. The catheters are placed under the same rigorous aseptic conditions as the rest of their surgery so no infections are expected.

Where is the study run from?

Hammersmith Hospital (UK)

When is study starting and how long is it expected to run for?

October 2014 to September 2016

Who is funding the study?
Imperial College Healthcare NHS Trust (UK)

Who is the main contact?
Dr Geoff Lockwood
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Contact information

Type(s)
Public

Contact name
Dr Geoff Lockwood

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Contact details
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W12 0HS

Additional identifiers

Protocol serial number
13HH1841

Study information

Scientific Title
A double blind, randomised controlled trial to assess the efficacy of bilateral paravertebral blockade for analgesia after cardiac surgery

Study objectives
Do paravertebral blocks provide useful analgesia by blocking specific nerves or are we simply seeing the systemic effects of the local anaesthetics as they are absorbed into the circulation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London (Dulwich), 08/08/2014, ref: 14/LO/0864

Study design
Single centre interventional randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Postoperative pain

Interventions

Bilateral paravertebral blockade or sham infusion of lidocaine

Intervention Type

Procedure/Surgery

Primary outcome(s)

Morphine consumption using a PCA device

Key secondary outcome(s)

1. Pain (measured using ordinal scale) and respiratory function (PEFR) for first 7 days
2. Quality of life, measured using the EuroQol EQ-5D questionnaire at 3 months

Completion date

14/09/2016

Eligibility

Key inclusion criteria

1. Age 40-70 years
2. Undergoing elective and urgent first time coronary bypass surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Critical preoperative state
2. Single graft surgery (no leg incision)
3. Minimally invasive surgery (no sternotomy)
4. Significant renal disease (baseline creatinine >150 micromolar: morphine contraindicated)
5. Patients exceeding 110kg (4% of our operative population practical difficulties of positioning unconscious patients to place the block)
6. Pregnancy

7. Patients with chronic pain taking regular analgesic medication
8. Patients with a significant abnormality of coagulation
9. Participation in another interventional study
10. Patients unable to give informed consent
11. Hypersensitivity to lidocaine

Date of first enrolment

26/10/2014

Date of final enrolment

07/09/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Hammersmith Hospital**

Ducane Road

London

United Kingdom

W12 0HS

Sponsor information

Organisation

Imperial College Healthcare

ROR

<https://ror.org/056ffv270>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Imperial College Healthcare NHS Trust

Alternative Name(s)

Imperial NHS, imperialnhs, Imperial College Healthcare NHS Trust | London

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/10/2017 | | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |